REMARKS

Claims 27, 32 and 37 are cancelled. Claims 1, 10, 41 and 50 are amended. Claims 1-26, 28-31, 33-36 and 38-52 are pending. The amendments to claims 1, 10 and 41 are supported by the specification at page 3, lines 2-5. The amendment to claim 50 corrects an inadvertent typographical error. No new matter is added.

INTERVIEW SUMMARY

Applicants would like to thank Examiner Russel for the helpful telephone discussion with Applicants' representative on June 6, 2005. During this discussion, independent claims 1, 10 and 41 were reviewed with respect to an amendment reciting the burst release characteristics of the claimed compositions. A Declaration under 37 CFR 1.132 describing the surprising and unexpected nature of these burst release characteristics was also discussed.

REQUEST FOR RECONSIDERATION

Clinically, recombinant human grown hormone (rhGH) is administered daily in growth hormone deficient patients. To decrease the dosing frequency and increase patient compliance, sustained release formulations have been under development. These formulations have the potential to allow patients to decrease their dosing interval from daily to once or twice per month. The present invention is drawn to a sustained release composition that uses a liquid carrier material (specifically, a non-polymeric, non-water soluble liquid material having a viscosity of at least 5,000 cP at 37°C that does not crystallize neat under ambient physiological conditions) to deliver multivalent metal cations and growth hormone. This composition provides a sustained release having a very low burst within 24 hours of administration, followed by protein release over 28 days.

The rejection of the claims under 35 U.S.C. § 103 over European Patent Application 0 216 485 (EP '485) in view of U.S. Patent No. 5,747,058 (Tipton et al.) has been obviated by appropriate amendment. Independent claims 1, 10 and 41 have been amended to recite that the composition comprising growth hormone releases at most 4% of the growth hormone *in vitro* within the first 24 hours, as determined by Release Rate Determination. This Release Rate Determination test is disclosed in the specification at page 4, lines 8 -17.

The low initial burst release of the claimed compositions is surprising and unexpected in view of EP '485 and Tipton et al. In the attached Declaration under 37 CFR 1.132, inventor Franklin Okumu states that the initial burst release of the claimed compositions is unexpectedly low in view of the disclosures of the cited references. The initial burst release of the claimed compositions is reduced by 10 fold relative to similar compositions that do not contain a multivalent cation. As noted in MPEP § 716.02(a), unexpected results are evidence of nonobviousness. Accordingly, claims 1-26, 28-31, 33-36 and 38-52 are not obvious over the cited references. Applicants respectfully request that this rejection be withdrawn.

Applicants submit that the present application is now in condition for allowance. Early notice of such action is earnestly solicited. Should the Examiner feel a discussion would expedite the prosecution of this application, for example a discussion regarding an Examiner's Amendment to the claims, the Examiner is kindly invited to contact the undersigned at (312) 876-1400.

Respectfully submitted,

Dated: 8 July 2005

Paul E. Rauch, Ph.D.
Registration No. 38,591

Evan Law Group
566 West Adams St., Suite 350
Chicago, IL 60661
(312) 876-1400